K083556

510(K) SUMMARY

FEB 19 2009

1. SUBMITTER:

Scandimed International
Korsdalsvej 125
DK-2610, Roedovre, Denmark
Establishment Registration Number: 3003376126
Official contact: Mr. Salah Chami, CEO
Telephone: 011-45-4492-6444
Date Prepared: November 24, 2008

2. DEVICE:

Tradename:	Auto-Band Ligator
Classification Name:	Hemorrhoidal Ligator
Classification:	Class II
Product Code:	78 MND
Regulation Number:	876.4400
Classification Panel:	Gastroenterology

3. PREDICATE DEVICE:

This Special 510(k) Premarket Notification is being submitted for a material formulation change to the ligation bands and to expand the product line to include 6 and 8 band variations. The predicate device used to determine substantial equivalence for this device was the Scandimed International Auto-Band Ligator (#K031236 and #K081142).

4. DEVICE DESCRIPTION:

The Scandimed Auto-Band Ligator consists of a ligator wheel head mounted on a scope fixation arm and connected by a stainless steel thread to the band barrel.

The only modifications being proposed in this current Special 510(k) Premarket Notification are to change the latex formulation of the rubber ligating bands and to expand the product line to include 6 and 8 band variations.

The Auto-Band Ligator incorporates the following product features:

- Automatic Reverse Movement to START position after each release
- Snap Fixation system ensures stable fixation on the scope
- Adjustable Snap Fixation System facilitates fixation on all brands of scopes
- Precision One-Step Release Mechanism of bands
- Only a single band can be released at a time
- Latex or Latex Free Rubber Bands
- Available in 5, 6, 7, 8 or 10 band configurations

5. INTENDED USE:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon. For single use only.

6. INDICATIONS FOR USE:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon. For single use only.

7. COMPARISON OF CHARACTERISTICS:

Comparisons of the proposed and predicate devices show that the technological characteristics such as materials, performance characteristics and packaging are identical or substantially equivalent to the currently marketed predicate devices.

8. PERFORMANCE DATA:

The Auto-Band Ligator was subjected to relevant performance testing. The results of the performance testing demonstrated the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scandimed International
c/o Mr. Stephen M. Page
Regulatory Consultant
MedReg Associates
29 Frigate Street
JAMESTOWN RI 02835

FEB 19 2009

Re: K083556
Trade/Device Name: Auto-Band Ligator
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: MND
Dated: January 16, 2009
Received: January 21, 2009

Dear Mr. Page:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): #K083556

Device Name: Auto-Band Ligator

Indications for Use:

The Auto Band Ligator is used to band esophageal varices or hemorrhoids in the colon.

For single use only.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083556

(Posted November 13, 2003)